

REMARKS

Claims 1, 2 and 5-7 are pending in the present application. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

Interview Summary

Applicants' representatives, Dan Altman and Neil Bartfeld, would like to thank Examiner Perreira for the courtesy extended to them during the telephonic interview conducted on June 15, 2010. The substance of this interview is reflected in the amendments and remarks presented herein.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 2 and 5-7 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* 46:3875-3878, 1998) in view of Suzuki et al. (*J. Agric. Food Chem.* 48:5649-5653, 2000) and in further view of Iwasaki et al. (US 7,014,876).

The pending claims recite a method of reduction of triglyceride levels by administering a functional beverage (claim 1) or composition (claim 6) comprising the recited methylated catechins and extracted from the recited list of tea leaves. The present invention relates, in part, to Applicants' discovery that methylated catechins are unexpectedly much better than non-methylated catechins at reducing blood triglyceride (BTG) levels. Based on this unexpected discovery, they identified the varieties of tea listed in Claims 1 and 6 that have high levels of methylated catechins, and selected these teas for reducing triglyceride levels. The Examiner alleges that it would have been "obvious to try" to substitute the "green or black tea" of the Zeyuan reference with the Benihomare tea of Suzuki. However, nothing in the prior art would lead one of ordinary skill in the art to select the presently claimed types of teas, which have been specifically selected as teas containing high levels of methylated catechins..

Zeyuan et al. (*J. Agric. Food Chem.* 46:3875-3878, 1998)

The Examiner alleges that since Zeyuan et al. teaches that black and green tea extracts reduce blood triglycerides (BTG), it would have been obvious that any of the constituents of both green and black tea have BTG-reducing effects. However, Zeyuan et al. do not indicate which substance in the extract has a BTG-reducing effect. Moreover, Tables 2 and 3 of Zeyuan et al. show that although the difference in catechin content between green tea and black tea is large, the difference in BTG reduction is small (BTG was decreased an average of 33.3% by green tea, and by 25.0% by black tea). In addition, Table 2 of Zeyuan et al. shows that although tea leaves contain a

variety of catechins, it does not disclose or suggest any relationship between catechin type and BTG reduction effect. As such, Zeyuan teaches that the amount of catechins present in the tea is not correlated with the BTG-reducing effect. In view of this teaching, Zeyuan does not even suggest that any of the catechins within the green and black teas are responsible for their effect on reduction of BTG levels, much less that methyl catechins in particular have an unexpected effect.

Suzuki et al. (J. Agric. Food Chem. 2000, 48, 5649-5653)

Suzuki et al. disclose that EGCG3"Me and EGCG4"Me extracted from oolong tea leaves of Benihomare cultivar have anti-allergy effects, and that Benihomare tea contains O-methylated catechins. However, this reference neither teaches nor suggests that methylated catechins, such as EGCG3"Me and EGCG4"Me, have BTG-reducing effects.

Iwasaki et al. (US 7,014,876)

Iwasaki et al. describe a packaged beverage containing various catechins in an amount of 0.092 to 0.5 g/100 mL, and that green tea and oolong tea are employed as tea leaves. However, this reference does not disclose anything that might suggest that BTG levels are reduced by consuming a beverage containing 5 mg or greater/100 mL of methylated catechins according to present claim 1.

Nonobviousness over the cited combination of Zeyuan, Suzuki and Iwasaki

Although each of Zeyuan et al. and Iwasaki et al. discloses catechins extracted from tea leaves, the high levels of methylated catechins present in the green tea strains recited in the present claims are specific catechins that differ from the catechins described in Zeyuan et al. and Iwasaki et al. Based upon the lack of correlation between catechins and BTG-reducing effects shown in Zeyuan et al., a person of ordinary skill in the art would realize that the catechins present in the strains of tea tested by Zeyuan do not contribute to BTG reduction. Further, neither Suzuki et al. nor Iwasaki et al. disclose any relationship between methylated catechins and BTG reducing effects.

As further support that nothing in the prior art would suggest to one having ordinary skill in the art to select the particular green teas recited in Applicants' claims, Applicants refer to the Maeda-Yamamoto et al. reference (*Nippon Shokuhin Kagaku Kaishi* 48:64-68, 2009), which was discussed in Applicants' response filed July 1, 2009. This reference teaches that strongly fermented teas, such as black tea, contain only trace levels of EGCG" 3Me. Nevertheless, black

tea has a BTG reduction effect. Table 1 of this reference shows that many green teas do not contain the O-methylated catechins present in the strains recited in the present claims. Thus, this reference supports the conclusion that one having ordinary skill in the art would have no expectation that the recited strains of green tea would be unexpectedly beneficial in the lowering of triglyceride levels.

In view of the foregoing, the combination of references cited by the Examiner does not teach or suggest the use of the claimed methylated catechins for reduction of BTG levels. Consequently, since one of ordinary skill in that art would not have adjusted the amount of the methylated catechins to those appropriate for BTG reduction, one could not have arrived at the appropriate amount of the methylated catechin (5 to 30 mg/100 mL) as presently claimed) by using the recited strains of green tea, having high levels of methyl catechins.

As further evidence of the nonobviousness of the present claims over the cited references, enclosed is a Rule 132 Declaration of Mari Yamamoto, one of the inventors of the present application. The data provided in the Declaration show that Benifuuki tea (Test Beverage 1), which is one of the teas recited in present claims 1 and 6, contains a significant amount of catechins, including methylated catechins (6.8 mg/100 ml beverage), while Yabukita tea (Test Beverage 2), which is not recited in the present claims, contains catechins, but no methyl catechins. In addition, the barley beverage (Test Beverage 3), which contains no detectable levels of catechins, whether methylated or not, was included as a control. (Declaration, paragraphs 6 and 8, and Tables 1 and 3).

When the different beverages were tested for their ability to lower BTG levels, Test Beverage 1 exhibited a considerable reduction in BTG levels compared to both Test Beverages 2 and 3 (Declaration, paragraph 9 and Table 4). Importantly, the average triglyceride level in the group of test subjects was significantly lowered after six weeks of consuming Test Beverage 1 (the Benifuuki green tea), whereas triglyceride levels in test subjects were not significantly lowered after six weeks of consuming the Test Beverages 2 or 3 (Yabukita green tea or barley tea) (*Id.*). These results illustrate that the beverages containing methylated catechins have remarkable and unobvious effects of reducing triglyceride levels compared to beverages not containing methylated catechins. In particular, the green tea beverage obtained from a strain of tea containing significant amounts of catechins, but no methyl catechins (Yabukita green tea), performed no better in reducing BTG than the barley tea, which has no catechins at all. Thus, only the green tea beverage containing a significant level of methyl catechins had a significant effect on triglyceride levels. (Declaration, paragraph 10).

Nothing in the prior art would lead one having ordinary skill in the art to expect that methylated catechin-containing green tea would have such a superior result in lowering BTG compared to green tea lacking significant amounts of methylated catechins. These unexpected results are neither disclosed nor suggested by any of the cited references, either alone or in combination, could not have been predicted by one of ordinary skill in the art, and strongly support the nonobviousness of the present claims over the cited references. It is clear that in the absence of the inventors' own teachings, one having ordinary skill in the art would not have any reason to select the particular varieties of tea recited in the present claims out of all the many varieties of tea, or to select the recited methylated catechins at the recited levels, because such a person would not know to select the varieties that have high levels of methyl catechins, or that these compounds, at these levels, would have superior BTG reducing effects. It is only based on the disclosure of the present application that one of ordinary skill in the art would know to select specific varieties of tea, i.e. those with high levels of the recited methylated catechins at the recited levels, for the unexpected result of lowering BTG levels.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants submit that all claims are in condition for allowance. However, if minor matters remain, the Examiner is invited to contact the undersigned at the telephone number provided below. If any additional fees are required, please charge these to Deposit Account No. 11-1410. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the

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undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 10, 2010

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